Sheet 1 of 3

E FORM PTO-1449

U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE Attorney Docket No.

50150/055003

Serial No.

10/652,799

INFORMATION DISCLOSURE

STATEMENT BY APPLICANT

Applicant Filing Date Barry Eisenstein et al. August 29, 2003

(Use several sheets if necessary)

Group

(37 C.F.R. § 1.98(b))

IDS Filed

January 11, 2005

Customer No.

21559

U.S. PATENTS

Examiner's Initials	Patent Number or Patent Application No.	Issue Date or Publication Date	Patentee or Applicant	Class	Subclass	Filing Date (If Appropriate)
BF	6,506,407	1/14/03	Wantanabe et al.			· /
ŀ	6,488,962	12/3/02	Bemer et al.			
	6,340,475	1/22/02	Shell et al.			
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	6,316,433	11/13/01	Rose et al.			
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EXAMINER BLESSING TUBER DATE CONSIDERED 4-01-05						

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Sheet _2_ of _3 SUBSTITUTE 50150/055003 U.S. DEPARTMENT OF COMMERCE Attorney Docket No. (MODIFIED) PATENT AND TRADEMARK OFFICE Serial No. 10/652,799 Barry Eisenstein et al. Applicant INFORMATION DISCLOSURE August 29, 2003 STATEMENT BY APPLICANT Filing Date (Use several sheets if necessary) 1651 Group (37 C.F.R. § 1.98(b)) **IDS Filed** January 11, 2005 Customer No. 21559 FOREIGN PATENT OR PUBLISHED FOREIGN PATENT APPLICATION Publication Country or Class Subclass Translation Examiner's Document (Yes/No) Initials Number Date Patent Office OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PLACE OF PUBLICATION) Alfa et al., "Survey of Incidence of Clostridium difficile Infection in Canadian Hospitals and Diagnostic Approaches," J. Clin. Microbiol. 36:2076-2080 (1998). Anton et al., "Rifalazil Prevents and Treats Clostridium difficile-Associated Infection in Hamsters," Abstract ID No. 102471, Publishing ID No. T1741, presented at the American Gastroenterological Association Meeting. Anton et al., "Rifalazii Prevents and Treats Clostridium Difficile-Associated Infection in Hamsters." Abstract. presented at the Digestive Disease Weekly Annual Meeting, May 2003. Bartlett et al., "Clindamycin-Associated Colitis Due to a Toxin-Producing Species of Clostridium in Hamsters," J. Infect. Dis.136:701-705 (1977). Bartlett et al., "Treatment of Antibiotic-Associated Pseudomembranous Colitis," Rev. Infect. Dls. 6:S235-S241 Boon et al., "Studies with Temocillin in the Hamster Model of Antibiotic-Associated Colitis," Drugs 29 (Suppl. 5) 57-63 (1985). Buggy et al., "Therapy of Relapsing Clostridium difficile-Associated Diarrhea and Colitis with the Combination of Vancomycin and Rifampin," J. Clin. Gastroenterol. 9:155-159 (1987). **Declaration of Barry Eisenstein** Fekety, R. "Guidelines for the Diagnosis and Management of Clostridium difficile-Associated Diarrhea and Colitis," Practice Parameters Committee," Am. J. Gastroenterol. 92:739-750 (1997). Fujii et al., "In Vitro and In Vivo Antibacterial Activities of KRM-1648 and KRM-1657, New Rifamycin Derivatives," Antimicrob. Agents Chemother. 38:1118-1122 (1994). Gorbach et al., "Successful Treatment of Relapsing Clostridium difficile Colitis with Lactobacillus GG," Lancet 2:1519 (1987). Hirata et al., "In Vitro and In Vivo Activities of the Benzoxazinorifamycin KRM-1648 against Mycobacterium tuberculosis," Antimicrob. Agents Chemother. 39:2295-2303 (1995). Kelly et al., "Clostridium difficile Colitis," N. Engl. J. Med. 330:257-262 (1994). Klemens et al., "Activity of KRM-1648 in Combination with Isoniazid Against Mycobacterium tuberculosis in a Murine Model," Antimicrob. Agents Chemother. 40:298-301 (1996). Kunimoto et al., "Recurrent Clostridium difficile-Associated Colitis Responding to Cholestyramine," Digestion 33:225-228 (1986). Kurtz et al., "GT160-246, a Toxin Binding Polymer for Treatment of Clostridium difficile Colitis," Antimicrob. Agents Chemother, 45:2340-2347 (2001). Kyne et al., "Clostridium difficile," Gastroenterol. Clinics 30:1-25 (2001). BF Kyne et al., "Recurrent Clostridium difficile Diarrhoea," Gut 49:152-153 (2001). **EXAMINER** DATE CONSIDERED lessing tubara EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with the next communication to applicant.

Sheet 3 of 3 U.S. DEPARTMENT OF COMMERCE Attorney Docket No. 50150/055003 SUBSTITUTE FORM PTO-1449 PATENT AND TRADEMARK OFFICE (MODIFIED) Serial No. 10/652,799 **Applicant** Barry Eisenstein et al. INFORMATION DISCLOSURE STATEMENT BY APPLICANT Filing Date August 29, 2003 (Use several sheets if necessary) 1651 Group January 11, 2005 (37 C.F.R. § 1.98(b)) **IDS Filed** Customer No. 21559 OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PLACE OF PUBLICATION) Lai et al., Clostridium difficile-Associated Diarrhea: Epidemiology, Risk Factors, and Infection Control," Infect. В Control Hosp. Epidemiol. 18:628-632 (1997). Lenaerts et al., "Evaluation of Rifalazil in a Combination Treatment Regimen as an Alternative to Isoniazid-Rifampin Therapy in a Mouse Tuberculosis Model," Antimicrob. Agents Chemother. 44:3167-3168 (2000). Leung et at., "Treatment with Intravenously Administered Gamma Globulin of Chronic Relapsing Colitis Induced by Clostridium difficile Toxin," J. Pediatr. 118:633-637 (1991). McFarland et al., "Breaking the Cycle: Treatment Strategies for 163 Cases of Recurrent Clostridium difficile Disease," Am. J. Gastroenterol. 97:1769-1775 (2002). McFarland et al., "A Randomized Placebo-Controlled Trial of Saccharomyces boulardii in Combination with Standard Antibiotics for Clostridium difficile Disease," JAMA 271:1913-1918 (1994). McVay et al., "In Vitro and In Vivo Activities of Nitazoxanide Against Clostridium difficile," Antimicrob. Agents Chemother, 44:2254-2258 (2000). National Committee for Clinical Laboratory Standards, Methods for Antimicrobial Susceptibility Testing of Anaerobic Bacteria, Approved Standard M11-A5, 5th ed. (2001). Olson et al., Ten years of Prospective Clostridium difficile Associated Disease Surveillance and Treatment at the Minneapolis VA Medical Center 1982-1991," Infect. Control Hosp. Epidemiol. 15:371-381 (1994). Peterson et al., "Antimicrobial Agents in Clostridium Difficile-Associated Intestinal Disease," Antimicrob. Agents 115-127 (1991). Pothoulakis, C., "Pathogenesis of Clostridium difficile Associated Diarrhoea," Eur. J. Gastroenterol. Hepatol. 8:1041-1047, (1996). Pothouakis et al., "CP-96, 345, a Substance P Antagonist, Inhibits Rat Intestinal Responses to Clostridium difficile Toxin A But Not Cholera Toxin," Proc. Natl. Acad. Sci. 91:947-951 (1994). Pothoulakis et al., "Microbes and Microbial Toxins: Paradigms for Microbial-Mucosal Interactions II. The Integerated Response of the Intestine to Clostridium difficile Toxins," Am. J. Physiot. Gastronintest. Liver Physiol. 280:178-183 (2001). *Recommendations for Preventing the Spread of Vancomycin Resistance: Recommendations of the Hospital Infection Control Practices Advisory Committee (HICPAC)," Am. J. Infect. Control 23:87-94 (1995). Sambol et al., "Infection of Hamsters with Epidemiologically Important Strains of Clostridium difficile," J. Infect. Dis. 183:1760-1766 (2001). Samore, "Epidemiology of Nosocomial Clostridium difficile Diarrhoea," J. Hosp. Infect. 43:S183-S190 (1999). Teasley et al., "Prospective Randomised Trial of Metronidazole Versus Vancoymcin for Clostridium-difficileassociated Diarrhoea and Colitis," Lancet 2:1043-1046 (1983). Tedesco et al., "Approach to Patients with Multiple Relapses of Antibiotic-Associated Pseudomembranous Colitis," Am. J. Gastroenterol. 80:867-868 (1985). Wilcox et al., "Recurrence of Symptoms in Clostridium difficile Infection-Relapse or Reinfection?" J. Hosp. Infect. 38:93-100 (1998). Zimmerman et al., "Review Article: Treatment of Clostridium difficile Infection," Aliment, Pharmacol, Ther. BF 11:1003-1012 (1997).

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